APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
WHALEY, PABLO S

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/634,145	HENG ET AL.
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _31 January 2006_.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-27_ is/are pending in the application.

    4a) Of the above claim(s) _16 and 17_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-15 and 18-27_ is/are rejected.

7)☒ Claim(s) _1, 4, 22, and 23_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _04 August 2003_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

       1.☐ Certified copies of the priority documents have been received.

       2.☐ Certified copies of the priority documents have been received in Application No. _____.

       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _2/13/2004_.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election of Group I drawn to Claims 1-21 and 27 and Specie II-A, with traverse, filed 01/31/2006, is acknowledged. The specie election drawn to Specie I is hereby withdrawn for the expedience of prosecution. Applicants' arguments regarding Specie II-A and Specie II-B as not being "mutually exclusive" is not persuasive, as genetic and non-genetic factors are inherently mutually exclusive. Claims 16 and 17 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 22 and 23 have been amended to depend from claims 1 and 4. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/31/2006.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-15 and 18-27.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 2/13/2004 has been considered in part. A legible copy of Schaefer et al. has not been provided as required, therefore this reference has not been considered [See MPEP, Appendix R, Section 1.98].

OBJECTIONS

Claims 1, 4, 22, and 23 are objected to because of the following informalities: Claims 1, 4, 22, and 23 contain improper periods (e.g. "a. collecting..., b. selecting...") and should recite "(a) collecting..., (b) selecting.., etc. Appropriate correction is required.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15, 18-20, and 21-27 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-15, 18-20, and 22-27 are directed to methods which do not recite either a physical transformation of matter or result in a concrete, tangible, and useful result. For example, instant claim 1 recites steps drawn to collecting data, selecting a model, determining weights, and optimizing model parameters. No actual, concrete result is recited in the claims, nor is any result "produced" in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory.

Claim 21 is directed to an article of manufacture comprising a computer readable medium with computer executable instructions embedded thereon. Claiming a list of instructions (i.e. program) embedded on a physical medium without any functionality to perform the instructions is not statutory subject matter. For the reasons set forth above, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a "method for determining a statistical model" in the preamble. However, as claim 1 does not result in the determination of a "statistical model", it is unclear what steps are minimally required to achieve the purpose of the preamble. Clarification is requested.

Claim 1 recites the limitation "said data having like data of said second type" [step c]. There is insufficient antecedent basis for this limitation. Furthermore, it is unclear whether "like" is intended to mean same, related, or otherwise. Clarification is requested.

Claim 3 recites "said corresponding weights". There is insufficient antecedent basis for this limitation. Clarification is requested.

Claim 4 recites "reference group...sets of data having data of said second type like data of second type...from...population". As written, it is unclear in what way this limitation further limits the "reference group" with regards to second type data. Clarification is requested via clearer claim language.

Claim 7 recites "wherein a residual for the *i*-th one of said data." There is insufficient antecedent basis for "the *i*-th one of said data sets." Furthermore, it is unclear

whether applicant is referring to "said data" from the reference group or one of the other groups. Clarification is requested.

Claim 7 recites "the value of the indicator." There is insufficient antecedent basis for this limitation. Claim 1 recites "indicator of disease status." Claim 5 recites "value of one" and "value between zero and one". However, there is no recitation of "value of the indicator" in the instant claims. Clarification is requested.

Claim 13 recites "indicative of the representativeness". There is insufficient antecedent basis for "representativeness." Furthermore, it is unclear as to the applicant's intended meaning of "representativeness." Clarification is requested.

Claims 2, 5, 6, 8-12, 14, 15, and 23-26 are rejected as they depend either directly or indirectly from claim 1.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8-11, 13, and 19-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by Schoonjans (MedCalc, www.medcalc.be/manual/cox-regression.php , Copyright 1993, p.1-6).

Schoonjans teaches a statistical method and software package for modeling a hazard. More specifically, Schoonjans teaches:

- A collection of predictor variables X_1, ..., X_k , a baseline (i.e. reference) hazard value $H_0(t)$, and time-dependent risk coefficients b_i ,..., b_k [p.1], which correlates to a first data type, second data type, and indictor of disease as in instant claims 1, 9, and 21.

- A "hazard model" $H(t)$ for predicting the probability of a hazard (i.e. death, disease recurrence, etc.) based on Cox proportional-hazard regression [p.1], as in instant claims 1, 19, and 21.

- Coefficients "exp(b)" for covariates are included in the model if they are statistically significant [p.5, lines 2-8], which correlates to a plurality of "weights" as in instant claims 1 and 21 [step c].

- Coefficients that are not statistically significant are not included into the hazard model [p.5, lines 10-11], which is a teaching for "optimization" as in instant claims 1 and 21 [step d].

- Optimized hazard model data is fitted and displayed as "survival curves" [p.6], which is a teaching for "fitting...data sets of data to candidate model" as in instant claims 1 and 21 [step d].

- Subgroup variable for categorization of predictor variables into subgroups [p.3].

- Chi-square test statistic determines the overall model fit by testing model covariates [p.4], which correlates to a "goodness of said fitting" as in instant claim 3.

- A "hazard ratio" determined by a weighted sum for each data set [p.1], which is a teaching for an "adjustment factor" as in instant claim 13.

- Cox proportional hazard function *H(t)*, as in instant claim 10, modeled as an exponential summation [p.1], which correlates to equation for *h(u)* as in instant claim 11.

- Survival probability function *S(t)* [p.5], which correlates to *R(t)* as in instant claim 11. It is well known in the art that a cumulative density function (i.e. *R(t)*) = 1 − survivor function [Charlett, Introduction to survival analysis, Slide 46]. Furthermore, specification [0005] discloses that "it is known" that a cumulative disease risk function (i.e. R(t)) can be calculated from a hazard function *h(u)* expressed as an exponential summation.

- Above methods are computed and output for display [Figure, p. 4], which correlates to a "computing system" as in instant claim 20.

Claims 1, 2, 4, and 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lloyd et al. (Annu. Rev. Public Health, 1999, 20, p.145-157).

Lloyd et al. teach methods using time-dependent covariates in the Cox proportional-hazards regression model [Abstract]. More specifically, Lloyd et al. teach the following:

- Collecting data on current smoking status and total number of cigarettes smoked, and step-function values of 1 or 0 based on smoking status [p.147, Illustration 1, lines 1-10], which correlates to first and second data types and indicator as in instant claim 1(a).

- Modeling plasma levels over time as a function of dosing times, selected patient covariate values including weight, age, gender, and height (i.e. non-genetic), and measures from kidneys and liver test (i.e. genetic) [p.149, lines 7-11], as in instant claims 1(b), 2, and 4(a). It is noted that grouping of data is inherent.

- Model includes fixed parameters to be estimated that is a multiplier of time-dependent covariates associated with statistical significant [p.149, lines 23-27], which is a teaching for a "candidate statistical model" and "weights associated with statistical significance" as in instant claim 1(c).

- Computer software for determining goodness-of-fit [p.152, Discussion], as in instant claims 1(d) and 10.

- Baseline lipid values to allow for adjustment of patient covariate data [p.148, lines 6-8], which is a teaching for a reference data group as in instant claim 4(a).

- Modeling risk as a moving weighted average of the values over time [p.148, lines 20-25], which is a teaching for 'group weights' as in instant claim 4(b).

- Cox proportional hazard model $\lambda(t|Z)$ [p.153], as in instant claim 10, and survival function $S(t|Z)$ [p.153], which correlates to as in instant claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being made obvious by Kirchberg et al. (In Proc. International ECCV Workshop on Biometric Authentication, June 2002, p.103-111), in view of Montomoli et al. (Genetic Epidemiology, 2002, 22, p.265-271).

Kirchberg et al. teach an optimization approach to creating and successively improving a model by means of genetic algorithms [Abstract]. More specifically, Kirchberg et al teach the following aspects of the instant invention:

- A collection of data points from a given image and from extracted edge feature points (2-D) [p.104, lines 1-12], which correlates to a first and second data types as in instant claim 1(a).

- A metric for determining distance between two data points [p.104, paragraph 7], which correlates to a "indicator" as in instant claim 1(a).

- Development of a 'face model' consisting of feature points [p.104, paragraph 4], as in instant claim 1(b).

- Normalization of data points (i.e. weights) [EQN (1)], as in instant claim 1(c).

- Formula for calculating distance value and best matching position and scale [EQN (2)], which correlates to a

- Fitness function taking into account the norm (i.e. weights) and graphs displaying goodness-of-fitting [EQN (3) and Fig. 7], as in instant claims 1(d) and 3.

Kirchberg et al. do not teach non-genetic and genetic data types, as in instant claim 2. However, Kirchberg et al. suggest genotype coding and individual survivability [Kirchberg et al., Section 3, paragraph 3, and Section 3.2].

Montomoli et al. teach a methods of determining multiple sclerosis recurrence risk using genetic and non-genetic factors [Abstract]. Montomoli et al. also model failure rate based on sex and age by fitting a Cox proportional hazard model, as in instant claim 2.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to incorporate the non-genetic and genetic data types with the optimization method of Kirchberg et al., where the motivation would have been to determine the importance of the genetic and environmental factors in disease recurrence [Montomoli et al., p.268, Discussion], resulting in the practice of the instant claimed invention with a reasonable expectation of success.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARY K. ZEMAN
PRIMARY EXAMINER